REMARKS

Claims 1, 2, 11-14, 23-31 are pending. Claims 1, 2, 11-14 and 23-31 are rejected. Claims 1, 2, and 11 are canceled without prejudice. New claims 32 and 33 are added.

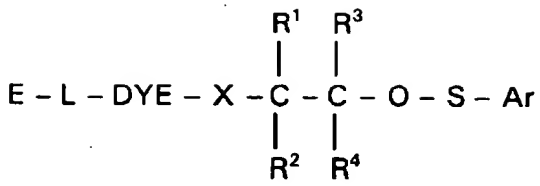
CLAIM REJECTIONS UNDER 35 U.S.C. § 112

The rejections under 35 U.S.C. § 112 form the only bases of rejections; namely, that claims 1, 2, 11-14, and 23-30 are rejected under 35 U.S.C. § 112 ¶¶ 1 and 2 as indefinite, not described, and not enabled; claim 31 is rejected under 35 US.C. § 112 ¶ 1. Applicants respectfully disagree.

Applicants have canceled without prejudice the pending composition claims (1, 2, 11). Thus, the issue is whether the method claims are adequately definite, described, and enabled.

For the following reasons, applicants assert the claims are adequately definite, described, and enabled, and respectfully request the Examiner's consideration. Independent claim 12 is directed to a method of performing a phototherapeutic procedure. Step (a) of claim 12 requires administering to a target tissue an effective amount of the claimed formula in a pharmaceutically acceptable carrier. The claimed formula has a sulfenate (-O-S-R) and a photosensitizer (a chromophore with high absorptivity that is activated by an appropriate wavelength of light, page 3, lines 3-6; page 12, lines 11-14). Step (b) of claim 12 requires exposing the target tissues to light to cause necrosis or apoptosis of the tissue (i.e., using the recited wavelength, having sufficient power, having sufficient fluence rate).

The claimed formula is



It contains -O-S-R sulfenate that produces free radicals upon photoactivation; it also contains Ar aromatic chromophore that undergoes photosensitization (page 12, lines 11-14). It contains core and substituent groups X, DYE, L, E, and R groups, each of which are defined in claim 12. X and L are spacer groups or linker groups, DYE is a cyanine radical, and E is an epitope.

To applicants best understanding and belief, all of the Examiner's rejections (each of items 8-16 at pages 5-18 of the Office Action) are based upon whether epitope E is adequately definite, described, and enabled.

Applicant has attempted in prior responses, and in the Rajagopalan Declaration, to explain that E targets the chemical to a tissue, that is, it serves a targeting function. The phototherapeutic method is achieved by the sulfenate, chromophore, and dye components of the formula. That is, E directs the compound to a target site requiring therapy, but does not effect the therapy.

To practice the method, Claim 12 affirmatively requires the step of targeting the compound. Specifically, step (a) affirmatively requires "administering [the compound] to a target tissue in an animal..."; step (b) requires "exposing said target tissue with light ...". The formula's targeting feature is stated in the claim itself, apart from any definition of E. Thus, applicants respectfully assert that the method claims, the only claims pending, are adequately described, supported and enabled with respect to

the method of performing the procedure. They are addressed by applicant's recitation that the photosensitizers are administered to a target tissue, and that the target tissue is exposed to light. Applicants also respectfully request consideration of new claims 32 and 33 in this respect, and assert no new matter has been added as the claims are fully supported by at least Figure 1, at page 12, lines 17-18, and at page 14, line 21 to page 15 line 2.

Applicants further respectfully disagree with the Examiner's characterizations, for example, that the claims are not enabled because performing the method would require clinical trials of the lack of a light source, and that it is "simply illogical" that tumors could be treated by phototherapy.

Regarding clinical data, applicants respectfully disagree with the Examiner's contention; these requirements are unnecessary for a determination of patentability. Such assessments would be akin to Phase II FDA submission requiring safety, efficacy and toxicity data, which the Federal Circuit has explicitly stated is not required. *In re Brana*, 51 F.3d 1560, 34 USPQ 2d 1436 (Fed. Cir. 1995)(copy attached). In *Brana*, the Examiner and the Board of Patent Appeals and Interferences ("Board") both discussed § 101 of the Patent Act, and the rejection involved appeared to be based on the issue of whether compounds had practical utility. *Id.* at 1439. However, the rejection, according to the Board, was based on the requirements of § 112, ¶1. *Id.* Thus, the *Brana* court noted an analogy between the utility of 35 USC § 101 and utility for enablement under § 112 ¶ 1, noting that if a claimed invention does not have utility, a specification certainly cannot enable one to use it. *Id.*

Regarding treatment, instrumentation such as a fluorescence endoscope is available, as known to one skilled in the art, to provide a light source.

Applicants have made a good faith attempt to address all of the Examiner's rejections. Should the Examiner believe any rejections remain outstanding, however, the Examiner is invited to contact applicants' undersigned representative.

CONCLUSION

For the foregoing reasons, applicants submit that all the rejections have been overcome and that the application is in condition for allowance.

Applicants do not believe any fee is due with this submission. Should any fee or surcharge be deemed necessary, the Examiner is authorized to charge fees or credit any overpayment to Deposit Account No. 23-3000.

The Examiner is invited to telephone applicants' undersigned representative if there are any questions.

Respectfully submitted,

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